sample measurements. If the arithmetic mean of each set of six samples is not within 10% of the overall arithmetic mean, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the overall arithmetic mean.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, shall be accurate to within ±25% at a 95% confidence level for concentrations of the PMN substances ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substances across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be

reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (0.5 x NCEL < > 1 x NCEL); one times the NCEL (1 x NCEL); between one and two times the NCEL (1 x NCEL < > 2 x NCEL), and twice the NCEL (2 x NCEL).

(II) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company shall conduct both an initial instrument calibration and a continuing calibration. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall within $\pm$ 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Company must calculate the percent of the PMN substances recovered by the analytical method from a sample containing a known quantity of the PMN substances. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor

pressure, by injecting the PMN substances onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substances must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substances onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substances in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substances is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substances at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated coefficient of variation is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value 30 $mg/m^3/(0.75)$ = 40 mg/m^3 when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs

(c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with light-sensitive PMN substances; or introduction of water/increased humidity to the workplace which could react with the PMN substances and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the PMN substances, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company shall take representative samples of

what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substances would be if respirators were not worn. The Company shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substances is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for

each exposure group.

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substances for each exposure group in which persons are reasonably likely to be exposed to the PMN substances.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substances are not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substances are not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 3 month period does not constitute grounds for postponement of the

3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substances are manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substances are manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substances;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substances; and

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the PMN substances.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any

corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the PMN substances will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Record-keeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substances and must be obtained under conditions closely resembling the types of materials, processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the PMN substances. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substances, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substances for any person who is reasonably likely to be exposed to the PMN substances by inhalation exceeds the NCEL, the Company shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the PMN substances at a workplace in accordance with this New Chemical Exposure Limit section, the Company shall comply with the respirator requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substances by inhalation use, at a minimum, the respiratory protection which corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured)

Measured Concentration of PMN Substance	**Required Respiratory Protection**

≤ NCEL -- No respiratory protection is required.

≤ 10 x NCEL *If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

-- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

-- NIOSH-certified powered air-purifying respirator equipped with a loose fitting hood or helmet and equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

≤ 25 x NCEL *If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

-- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

-- NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

≤ 50 x NCEL *If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:*

-- NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with the appropriate gas/vapor cartridges (organic vapor, acid gas, or substance-specific).

If No Cartridge Service Life Testing is Available:

-- NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting full facepiece.

≤ 2000 x NCEL -- NIOSH-certified supplied-air respirator operated in pressure demand or

other positive pressure mode and equipped with a tight-fitting full facepiece.

> 2000 x NCEL -- Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.

-- Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substances is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the lower quantitation limit ("LQL") of the analytical method (as described in paragraph (c)(4)(ii)) is

measured, the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the actual upper quantitation limit ("UQL") of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company shall maintain the following records until 30 years after the date they are created, and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence

of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the American Industrial Hygiene Association ("AIHA") or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substances;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substances;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

MANUFACTURING

(a) (1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

CONTROL OF EFFLUENT & EMISSIONS

(a) The Company shall recover and capture (destroy) or recycle the PMN substances at an overall efficiency of 99% from all the effluent process streams and the air emissions (point source and fugitive).

DISTRIBUTION

(a) Distribution Requirements. Except as provided in paragraph (b), the Company shall distribute the PMN substances outside the Company, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order;

(2) Distribute the PMN substances only to a person who will either recover and capture (destroy) or recycle the PMN substances from all effluent process streams and air emissions (point source and fugitive) at an overall efficiency of 99%; and

(3) Distribute the PMN substance P-08-509 in an aqueous dispersion of the polymer product or on a heat treated solid product such that the contents polymer residual P-08-508/509 cumulative total [ ] are below 200 ppb level using the ASE method developed by Larsen et al[1] with the level of quantification (LOQ) for the standard solution at 0.5 ppb. If non-heat treated solid polymer is distributed by the Company, such person shall not further distribute until heat treatment is performed at temperature and residence time sufficient to produce a product with P08-508/509 cumulative residual levels equivalent to the heat treated

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[1]Larsen et al, "Efficient "total" extraction of perfluorooctanoate from polytetrafluoroethylene fluoropolymer", *Analyst*, 2006, 131, 1105-1108.

polymer distributed by the Company, (i.e., below 200 ppb).

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Company may distribute the PMN substances outside the Company for temporary transport and storage in sealed containers provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substances may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (a).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (a).

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substances, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section or, after paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a significant new use of the PMN substances (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substances without

submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substances and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (c)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (a)(1) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substances and paragraph (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Company shall notify each person to whom it distributes the PMN substances of the existence of the SNUR. Such

notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for this PMN substances in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so that, if the Company provides such notice to the persons to whom it distributes the PMN substances, then the Company is not required to obtain from such persons the written agreement specified in paragraph (a).

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for

5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substances;

(7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

(8) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(9) Records documenting compliance with the Control of Effluent & Emissions section of this Order;

(10) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(11) The Company shall keep a copy of this Order at each of its sites where the PMN substances are manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may ocassionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such

inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of

TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full

interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that

determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

1/26/09
Date

/s/
Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

1/28/09
Date

/s/
Name: James R. Hoover

Title: Global Regulatory Manager

Company: DuPont Company

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

STATISTICAL ANALYSIS OF NCELs ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum(\bar{X}_{ij} - X_i)^2/(n_i - 1),\ i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2)/(W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2/[W_1^2/(n_1 - 1) + W_2^2/(n_2 - 1)]$$

where,

$W_1 = S_1^2/n_1,\ i = 1, 2$

$\bar{X}_1$ = Average of the results from the company laboratory

$\bar{X}_2$ = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured

by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be a integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$\bar{X}_1 = 83.30$ $n_1 = 6$ $\bar{X}_2 = 100.40$ $n_2 = 6$

$S_1^2 = 278.72$ $W_1 = 46.25$ $S_2^2 = 9.26$ $W_2 = 1.54$

Absolute value of $T = 2.467$ $f = 5.33$

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$\bar{X}_1 = 95.37$ $n_1 = 6$ $\bar{X}_2 =$ 104.37 $n_2 = 6$

$S_1^1 = 65.59$ $W_1 = 10.93$ $S_2^2 = 27.25$ $W_2 = 4.54$

Absolute value of $T = 2.290$ $f = 8.54$

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

ATTACHMENT C

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official	Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone

To: Hall, Renea[Hall.Renea@epa.gov]
From: Allenbach, Becky
Sent: Wed 10/25/2017 9:01:59 PM
Subject: FW: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26
2017-09-05 GenX NCDEQ Notice of Intent to Suspend NPDES.pdf
2017-10-24 GenX NCDEQ Letter Not to Suspend NPDES.pdf

Fyi.....

Becky B. Allenbach, Chief
Grants and Drinking Water Protection Branch
Water Protection Division
EPA Region 4 - Atlanta
Office: 404-562-9687
Cell: **Personal Phone / Ex. 6**

From: Speir, Jeffrey
Sent: Wednesday, October 25, 2017 4:51 PM
To: Allenbach, Becky <Allenbach.Becky@epa.gov>
Subject: RE: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26

Great, thank you for this information. I will let the call organizers know that regional Air, OAQPS, or ORD may be best positioned to provide that update.

I just received a news alert today regarding NC DEQ's decision not to suspend the NPDES permit. I have attached the state's letter, which was sent yesterday. I have also attached the original letter from the state, which set out the possibility of NPDES permit suspension.

I will be sure to direct future messages to you and Renea Hall.

Thanks again!

Jeffrey Speir
Attorney-Adviser
U.S. Environmental Protection Agency
OECA – OCE – Water Enforcement Division
1200 Pennsylvania Avenue, NW (2243-A)
Washington, DC 20460
(202) 564-0872

From: Allenbach, Becky
Sent: Wednesday, October 25, 2017 4:39 PM
To: Speir, Jeffrey <speir.jeffrey@epa.gov>
Subject: RE: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26

Hi Jeff:

I have been the gate keeper in Region 4 for the water related issues and participate on weekly update calls with NC DEQ. I was not aware of the information you mention in item #1. When did we receive that info? The air info was discussed on one of the weekly calls and I requested it and sent it to our regional Air and TSCA folks and to Maria Doa. I think our Air division might best be able to help with information and I know that OAQPS and ORD may be involved in additional air sampling planned by NC.

Please direct future messages to me and to my staff lead, Renea Hall.

I will do my best to call in tomorrow, but I am off that day and have several appointments.

I am teleworking today until 6 if you would like to discuss further. Call my cell below.

Becky B. Allenbach, Chief
Grants and Drinking Water Protection Branch
Water Protection Division
EPA Region 4 – Atlanta
Office: 404-562-9687
Cell: Personal Phone / Ex. 6

From: Speir, Jeffrey
Sent: Wednesday, October 25, 2017 4:25 PM
To: Allenbach, Becky <Allenbach.Becky@epa.gov>
Subject: FW: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26

Hi Becky,

I wanted to be sure that my message (below) also reaches you and your staff in the Grants and Drinking Water Protection Branch. If there is someone on your staff to whom I should direct similar future messages, please let me know.

As I mention below, please let me know if you would prefer that Region 4 take the lead on any of the subjects I identified for discussion tomorrow.

Thank you!

-Jeff

Jeffrey Speir
Attorney-Adviser
U.S. Environmental Protection Agency
OECA – OCE – Water Enforcement Division
1200 Pennsylvania Avenue, NW (2243-A)
Washington, DC 20460
(202) 564-0872

From: Speir, Jeffrey
Sent: Wednesday, October 25, 2017 4:04 PM
To: Schwartz, Paul <Schwartz.Paul@epa.gov>; Shell, Karrie-Jo <Shell.Karrie-Jo@epa.gov>; Fite, Mark <Fite.Mark@epa.gov>
Subject: RE: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26

Hi Paul, Karrie-Jo, and Mark:

I wanted to reach out to you (in ORC, WPD, and Enforcement) to give you a heads up that I plan to briefly discuss the following water-related developments on tomorrow's Chemours call: Enforcement/Investigatory / Ex. 7(a)

Enforcement/Investigatory / Ex. 7(a)

Please let me know if you, or anyone in Region 4, would prefer to take the lead on any of these subjects.

Also, HQ folks looking into the TSCA 5(e) order have expressed interest in the recent air emissions data from NC. I believe that this data came in to the WPD on October 17. Is there someone in Region 4 who could discuss this data on the call tomorrow?

Thanks!

-Jeff

Jeffrey Speir
Attorney-Adviser
U.S. Environmental Protection Agency
OECA – OCE – Water Enforcement Division
1200 Pennsylvania Avenue, NW (2243-A)
Washington, DC 20460
(202) 564-0872

From: Garvey, Mark
Sent: Wednesday, October 18, 2017 5:01 PM
To: Miles, James <miles.james@epa.gov>; Toney, Anthony <Toney.Anthony@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Star, David <star.david@epa.gov>; Tucker, Marlene <Tucker.Marlene@epa.gov>; Ellis, Tony <Ellis.Tony@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>; Saenz, Diana <Saenz.Diana@epa.gov>; Martinez, Jeffrey <Martinez.Jeffrey@epa.gov>; King, Carol <King.Carol@epa.gov>; Anderson, Kate <Anderson.Kate@epa.gov>; Bean, Mark <Bean.Mark@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Allison, Rose <Allison.Rose@epa.gov>; Swan, Russell <Swan.Russell@epa.gov>; Bookman, Robert <Bookman.Robert@epa.gov>; Pratt, Stacie <Pratt.Stacie@epa.gov>; daw, harry <daw.harry@epa.gov>; Gorman, John <Gorman.John@epa.gov>; Klevs, Mardi <klevs.mardi@epa.gov>; Kemker, Carol <Kemker.Carol@epa.gov>; Denton, Loren <Denton.Loren@epa.gov>; Paul Buellesbach <paul.buellesbach@erg.com>; Dan-Tam Nguyen <Dan-Tam.Nguyen@erg.com>; Daryl Hudson <Daryl.Hudson@erg.com>; Schulz, Susan <Schulz.Susan@epa.gov>; DeDora, Caroline <DeDora.Caroline@epa.gov>; Davis, Lauren O. <Davis.LaurenO@epa.gov>; Gordon, Scott <Gordon.Scott@epa.gov>; Fite, Mark <Fite.Mark@epa.gov>; George, Verne <George.Verne@epa.gov>; Bates, Keith <Bates.Keith@epa.gov>; Mitchell, Ken <Mitchell.Ken@epa.gov>; Pollins, Mark <Pollins.Mark@epa.gov>; Theis, Joseph <Theis.Joseph@epa.gov>; Bahk, Benjamin <Bahk.Benjamin@epa.gov>; Unger, LouAnn <unger.louann@epa.gov>; Bair, Rita <bair.rita@epa.gov>; Shoven, Heather <shoven.heather@epa.gov>; Field, Stephen <Field.Stephen@epa.gov>; Schwartz, Paul <Schwartz.Paul@epa.gov>; Davis, Molly <Davis.Molly@epa.gov>; Ireland, Laurie <Ireland.Laurie@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>; Poy, Thomas <poy.thomas@epa.gov>; Speir, Jeffrey <speir.jeffrey@epa.gov>; Collins, Charlie <collins.charlie@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; rogers, rick <rogers.rick@epa.gov>; Wilson, Jennifer <wilson.jenniferA@epa.gov>; Harris, Kimberly <harris.kimberly@epa.gov>; Clark, Jacqueline <clark.jacqueline@epa.gov>; Duchovnay, Andrew <Duchovnay.Andrew@epa.gov>; Day, Christopher <Day.Christopher@epa.gov>; Coe, Mary <Coe.Mary@epa.gov>; Ramalho, Louis <Ramalho.Louis@epa.gov>; Lewis, Jennifer <Lewis.Jennifer@epa.gov>; Baptista, Chrisna <Baptista.Chrisna@epa.gov>; Niess, Claudia <niess.claudia@epa.gov>; Spann, Tony <Spann.Tony@epa.gov>; Timsina, Gopal <Timsina.Gopal@epa.gov>; Allenbach, Becky <Allenbach.Becky@epa.gov>; Mancusi-Ungaro, Philip <Mancusi-Ungaro.Philip@epa.gov>; Bush, William <Bush.William@epa.gov>; Janovitz, Sara <Janovitz.Sara@epa.gov>; Hall, Renea <Hall.Renea@epa.gov>; Shell, Karrie-Jo <Shell.Karrie-Jo@epa.gov>; Devkota, Om <devkota.om@epa.gov>
Subject: RE: Chemours - Enforcement Coordination - Proposed Reschedule To Oct 26

To the EPA Staff Working on GenX Enforcement:

James Miles and I are proposing to push the conference call back a week since we have inspections occurring today in Region 3 at the Chemours use facility in Parkersburg WV. Region 4 is assisting Region 3 in that inspection. Unless anyone wants to have the call tomorrow, we would like to reschedule for the same time and same day next week. This will give us time to organize our thoughts on the information coming in on the Region 4 follow-up questions to its inspection as well as preliminary information on the Region 3 inspection.

I'm also attaching 3 items concerning GenX .

Enforcement/Investigatory / Ex. 7(a)

Again, let me know if you want to have the call tomorrow, otherwise, James will reschedule for next week.

Thanks,
Mark

Mark Garvey
EPA Headquarters
Office of Civil Enforcement
Attorney
202-564-4168
garvey.mark@epa.gov

-----Original Appointment-----
From: Miles, James
Sent: Friday, September 22, 2017 11:45 AM
To: Miles, James; Toney, Anthony; Doa, Maria; Star, David; Garvey, Mark; Tucker, Marlene; Ellis, Tony; Sullivan, Greg; Saenz, Diana; Martinez, Jeffrey; King, Carol; Anderson, Kate; Bean, Mark; Henry, Tala; Allison, Rose; Swan, Russell; Bookman, Robert; Pratt, Stacie; daw, harry; Gorman, John; Klevs, Mardi; Kemker, Carol; Denton, Loren; Paul Buellesbach; Dan-Tam Nguyen; Daryl Hudson; Schulz, Susan; DeDora, Caroline; Davis, Lauren O.; Gordon, Scott; Fite, Mark; George, Verne; Bates, Keith; Mitchell, Ken; Pollins, Mark; Theis, Joseph; Bahk, Benjamin; Unger, LouAnn; Bair, Rita; Shoven, Heather; Field, Stephen; Schwartz, Paul; Davis, Molly; Ireland, Laurie; Moyer, Adam; Poy, Thomas; Speir, Jeffrey; Collins, Charlie; Aubee, Catherine; rogers, rick; Wilson, Jennifer; Harris, Kimberly; Clark, Jacqueline; Duchovnay, Andrew; Day, Christopher; Coe, Mary; Ramalho, Louis; Lewis, Jennifer; Baptista, Chrisna; Niess, Claudia; Spann, Tony; Timsina, Gopal; Allenbach, Becky; Mancusi-Ungaro, Philip; Bush, William; Janovitz, Sara; Hall, Renea; Shell, Karrie-Jo; Devkota, Om
Subject: Chemours - Enforcement Coordination Call - TSCA CBI
When: Thursday, October 19, 2017 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Personal Phone / Ex. 6

Continuing bi-weekly call through Nov.

H-28548: Combined Chronic Toxicity/Oncogenicity Study
2-Year Oral Gavage Study in Rats

Work Request Number 18405

Service Code 1238

DuPont Report Number – 18405-1238

Protocol

June 28, 2010

TABLE OF CONTENTS

1. INTRODUCTION

1.1. Study Number

DuPont Work Request/Study Code Number: DuPont-18405/1238

DuPont Report Number: 18405-1238

MPI Research Study Number: 125-141

1.2. Study Title

H-28548: Combined Chronic Toxicity/Oncogenicity Study 2-Year Oral Gavage Study in Rats

1.3. Sponsor

E.I. du Pont de Nemours and Company
Wilmington, Delaware 19898, U.S.A.

1.4. Sponsor Representative

Susan A. MacKenzie, V.M.D., Ph.D., D.A.B.T.
Senior Research Toxicologist
DuPont Haskell Global Centers for Health and Environmental Sciences
P.O. Box 50
Newark, Delaware 19714 U.S.A.

Telephone: 302-366-6389
Telefax: 302-366-5211
E-mail: Susan.A.MacKenzie@USA.dupont.com

1.5. Objective

The objective of this study is to evaluate the potential chronic toxicity and oncogenicity of H-28548 when administered via oral gavage over the major portion of the life span of the test animals.

1.6. Regulatory Guideline

This protocol meets the United States Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances, Guideline 870.4300, Combined chronic toxicity/carcinogenicity, August 1998. The experimental design and methods are also based on the Organization for Economic Cooperation and Development (OECD) Guideline 453, September 2009, the Japanese Ministry of Agriculture, Forestry and Fisheries Guidelines for Data Requirements for Supporting Registration of Pesticides, No. 12-Nousan-8147, Notification by Director-General dated 24 November, 2000, and the Commission Directive 88/302/EEC B.33 Combined Chronic/Carcinogenicity test, *Methods for the Determination of Toxicity* (1988).

1.7. Good Laboratory Practice

This nonclinical laboratory study will be conducted in accordance with the United States Environmental Protection Agency FIFRA Good Laboratory Practice (GLP) Standards, 40 CFR Part 160, Toxic Substance Control Act Good Laboratory Practice Standards, 40 CFR Part 792, the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice ENV/MC/CHEM(98)17, and the Japanese Good Laboratory Practice Standards, 11 Nohsan No. 6283 and as changed in 12 Nohsan No. 8628, and 13 Seisan No. 1660.

1.8. Testing Facility

MPI Research, Inc.
54943 North Main Street
Mattawan, MI 49071-9399 U.S.A.

MPI Research is fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

1.9. Computer Systems

The following are the proposed computer systems to be used during the conduct of this study. The actual systems used will be documented in the final report.

MPI Research Computer Systems	
Provantis™:	Client-server, Oracle-based system primarily used for toxicology studies.
Niagara Framework® Software System or Siemens Environmental Monitoring System (EMS):	Environmental monitoring, alarming, and reporting application.
Dispense:	Automates the test article control processes.
Microsoft® Windows XP:	Used in conjunction with Empower 2 software
Empower 2:	Empower 2 Chromatographic Data System used to quantitatively determine the amounts of analytes in samples, including test articles in formulation.
MPI Archiving System (MArcS):	In-house developed application for automated storage and retrieval information for archiveable materials (e.g. lab books, study data, wet tissues, slides, etc.).
Enterprise Reporting System – Table Production System (TPS):	In-house developed reporting system used primarily for reporting of Provantis™ data.
Master Schedule:	Maintains the master schedule for the company.

SAS®:	The SAS® System is an integrated system of software products that enables a user to perform data entry, retrieval, data management, reporting, graphics, statistical analysis, and applications development.
Microsoft® Office 2003 Professional:	Bundle of integrated productivity tools including word and data processing and communications software. Contains the utilities Microsoft® Access, Excel, InfoPath, Outlook, PowerPoint, Publisher, and Word.
docuBridge®:	Electronic publishing system.

1.10. Personnel

1.10.1. Study Director

Lisa Craig, B.S.

Telephone: 269-668-3336 ext. 1367
Telefax: 269-668-4151
E-mail: lisa.craig@mpiresearch.com

1.10.2. Alternate Contact

Chris N. Papagiannis, B.S.

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Telefax: 269-668-4151
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1.11. Proposed Study Schedule

Study Initiation Date (EPA and OECD): (Date Study Director signs Study Approval-Initiation Line in the protocol)	Date Study Director signs Study Approval-Initiation Line in this protocol
Experimental Starting Date (OECD): (Date of the first data collection directly from the study)	To be added by amendment.
Experimental Start Date (EPA): (Date of first test article exposure)	To be added by amendment.
Experimental End Date (EPA): (Date of last animal termination)	To be added by amendment.
Experimental Completion Date (OECD): (Date of the last data collection directly from the study)	Date Anatomic Pathology Contributor report is signed
Draft Report Mail Date:	To be added by amendment

1.12. Quality Assurance

This study will be subjected to periodic inspections and the data, draft and final reports will be reviewed by the Quality Assurance Department of MPI Research in accordance with MPI Research's Standard Operating Procedures. Study quality assurance inspection records will be made available to the Sponsor Representatives during visits to MPI Research.

1.13. Alteration of Design

Alterations of this protocol may be made as the study progresses. No changes in the protocol will be made without the specific written request or consent of the Sponsor. In the event that the Sponsor authorizes a protocol change verbally, MPI Research will honor such change. However, written authorization will be obtained thereafter. All protocol amendments and justifications will be documented, signed, and dated by the Study Director and Sponsor. The protocol and all amendments will be issued to the Sponsor as well as at MPI Research.

1.14. Declaration of Intent

This study may be submitted to an Organization for Economic Cooperation and Development (OECD) member country, the United States Environmental Protection Agency (EPA), and/or other country regulatory bodies.

2. TEST AND CONTROL ARTICLES

2.1. Description of Test Article

2.1.1. Identity

HFPO Dimer Acid Ammonium Salt (aka H-28548)

Haskell number: 28548

R&D Lot Number: E109540-44A

A description, lot number, storage conditions, expiration date, safe handling procedures, physical properties, as well as other relevant information will be documented in the study data.

2.1.2. Test Article Properties

The Sponsor will provide a certificate of analysis (COA) documentation on the purity, composition, stability, and other pertinent information, unless otherwise noted.

2.2. Test Article Preparation

The bulk test article will be stored at room temperature. The test article formulations will be adjusted for a purity of 84%. The test article will be mixed with deionized water to achieve the desired dose volumes. The vehicle and method of preparation will be determined based upon physical characteristics of the test article and size of batches required. Fresh formulations will be prepared for each concentration weekly and stored ambient when not in use.